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Dated: January 25, 2010

Electronic Signature for William A. Di Bianca: /William A. Di Bianca/

**EXPEDITED PROCEDURE**

Group Art Unit: 3738

Docket No.: SPINE 3.0-437 CIPCIPCIPCIPCIPCON II

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	:
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Errico et al.	:
	:
Application No.: 10/784,637	: Group Art Unit: 3738
	:
	:
Filed: February 23, 2004	: Examiner: B. E.
	: Pellegrino
	:
	:
For: INSTRUMENTATION FOR PROPERLY	:
SEATING AN ARTIFICIAL DISC IN AN	:
INTERVERTEBRAL SPACE	:

**AMENDMENT UNDER 37 CFR § 1.116**

MS AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action dated  
September 25, 2009, finally rejecting claims **1-8, and 13-24**,  
please amend the above-identified U.S. patent application as  
follows:

**IN THE CLAIMS**

1. (currently amended) An apparatus for bringing baseplates of an artificial intervertebral disc substantially parallel to one another in an intervertebral space, the apparatus comprising:

at least one shaft having a distal end and a longitudinal axis; and

~~at least two~~ one pair of tines extending parallel to one another from the shaft distal end in a same direction as that of the longitudinal axis, the ~~at least two~~ tines forming a central pocket forward of the shaft distal end between the ~~at least two~~ tines, the ~~at least two~~ tines having a flat top surface and a curved bottom surface;

wherein the disc comprises ~~at least two~~ an upper baseplate and a lower baseplates coupled to one another by a central coupling between the baseplates, which coupling permits the baseplates to articulate relative to one another, including articulating such that the baseplates are substantially non-parallel to one another and including articulating such that the baseplates are substantially parallel to one another, the baseplates being separated from one another by a separation space volume when the baseplates are substantially parallel; and

wherein the tines are spaced and sized to be insertable and fittable between the baseplates, wherein the central coupling is located between the ~~at least two~~ tines during the insertion and when so fitted, such that when the baseplates are substantially non-parallel to one another in the intervertebral space, insertion of the tines into the intervertebral space between the baseplates forces the baseplates into a substantially parallel orientation relative to one another as the flat top surface of the ~~at least two~~ tines contacts an flat inwardly facing surface of ~~one of the at least two~~ the upper baseplates and the curved bottom surface of the

~~at least two~~ tines contacts an curved inwardly facing surface of the ~~other of the at least two~~ lower baseplates.

2. (original) An apparatus according to claim 1, wherein at least one of the baseplates has at least one spike, and wherein bringing the baseplates into a substantially parallel orientation relative to one another includes securing a purchase of at least one of the spikes to at least one vertebral bone.

3. (original) An apparatus according to claim 1, further comprising a handle coupled to the shaft; wherein applying pressure to the handle in a distal direction aids insertion of the tines between the baseplates in the intervertebral space; and

wherein applying pressure to the handle in a proximal direction aids extraction of the tines from between the baseplates out from the intervertebral space.

4. (original) An apparatus according to claim 1, further comprising at least one vertebral body stop that prevents over-insertion of the tines into the intervertebral space.

5. (currently amended) An apparatus according to claim 1, wherein a distal end of ~~at least one of the tines is~~ are tapered to ease insertion of the ~~at least one of the tines~~ between the baseplates.

6-12. (cancelled).

13. (previously presented) An apparatus according to claim 1, wherein the central coupling comprises a ball and socket structure.

14. (currently amended) An apparatus according to claim 13, wherein the ball and socket structure comprises a post projecting from an inner surface of a first one of the ~~at least two~~ baseplates and a ball having a blind opening that is adapted to receive the post.

15. (currently amended) An apparatus according to claim 14, wherein the ball and socket structure comprises a socket formed in an inner surface of a second one of the ~~at least two~~ baseplates.

16. (currently amended) An apparatus according to claim 1, wherein the central coupling consists of a single coupling that interconnects the ~~at least two~~ baseplates.

17. (currently amended) A system for inserting an artificial intervertebral disc into an intervertebral space comprising:

first and second baseplates coupled together by a central coupling extending between said baseplates, wherein said central coupling is centrally located between said baseplates and enables said baseplates to rotate and articulate relative to one another, the baseplates being separated from one another by a separation space volume when the baseplates are substantially parallel;

an insertion tool including a shaft having a proximal end, a distal end, a longitudinal axis extending between the proximal and distal ends, and ~~a one~~ pair of tines extending from the distal end of said shaft, said pair of tines forming a central pocket forward of said shaft distal end between said pair of tines, wherein said tines extend along axes that are parallel to

one another, the ~~at least two~~pair of tines having a flat top surface and a curved bottom surface;

wherein said pair of tines are spaced and sized for insertion between said first and second baseplates such that said central coupling is located between said pair of tines so that when said baseplates are substantially non-parallel to one another, insertion of said tines between said baseplates forces said baseplates into a substantially parallel orientation relative to one another as the flat top surface of the ~~at least two~~pair of tines contacts an flat inwardly facing surface of ~~one of~~ the ~~at least two~~first baseplates and the curved bottom surface of the ~~at least two~~pair of tines contacts an curved inwardly facing surface of the ~~other of the at least two~~second baseplates, the tines being spaced and sized to be insertable and fittable between the baseplates.

18. (previously presented) The system as claimed in claim 17, wherein said insertion tool comprises at least one vertebral body stop that prevents over-insertion of said tines into the intervertebral space.

19. (currently amended) The system as claimed 17, ~~wherein at least one contact surface of at least one of said tines contacts a corresponding surface of one of said baseplates during insertion, and wherein the at least one contact surfaces of said tines~~ has a shape that conforms to a shape of the corresponding surface of ~~one of said~~the baseplates.

20. (cancelled).

21. (previously presented) The system as claimed in claim 17, wherein said central coupling comprises a ball and socket structure.

22. (previously presented) The system as claimed in claim 21, wherein said ball and socket structure comprises a post projecting from an inner surface of said first baseplate and a ball having a blind opening that is adapted to receive said post.

23. (previously presented) The system as claimed in claim 22, wherein said ball and socket structure comprises a socket formed in an inner surface of said second baseplate.

24. (previously presented) The system as claimed in claim 17, wherein said central coupling consists of a single coupling that interconnects said first and second baseplates.

**REMARKS/ARGUMENTS**

The present communication is responsive to the Final Office Action mailed September 25, 2009. A one-month extension of time, extending the period of reply from December 25, 2009 up to and including January 25, 2010 is submitted herewith along with a Request for Continued Examination.

Claims 1, 5, 14-17, and 19 have been amended herein. Claims 6-8 and 20 are cancelled and no claims have been added herein. Therefore, claims 1-5 and 13-19, and 21-24 are now pending in the present application. Support for all claim amendments can be found in Applicants' originally filed disclosure in at least paragraph [0146]. As such, no new matter has been added. Applicants set forth remarks relating to the Office Action below.

Applicants note that the Petition under 37 C.F.R. § 1.78(a)(3) to Correct Priority Information has been granted since the present Office Action was mailed.

In the Action, claims 17-24 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner rejected claims 17-24 asserting that claim 17 lacks sufficient antecedent basis for the claim limitation "at least two times." Claim 17 is amended herein to recite the "pair of times" in each place where the "at least two times" limitation was previously presented. Applicants respectfully assert that the § 112, second paragraph rejections of the claims is overcome and request that it be withdrawn.

Further in the Action, the Examiner rejected claims 1-6, 13-19, and 21-24 under 35 U.S.C. § 102(e) as being anticipated by U.S. Pat. Pub. No. 2004/143332 to Krueger *et al.* ("Krueger"), and claims 7, 8, and 20 under 35 U.S.C. § 103(a) as

obvious in view of Krueger. Basically, the Examiner is of the opinion that Krueger teaches each and every limitation of independent claims 1 and 17, and asserted that the apparatus disclosed in Krueger includes a tool part having two tines 242 forming a central pocket therebetween. The Examiner further asserted that Krueger shows the insertion apparatus assembled with the tines being forward of the shaft distal end and inserted between the baseplates to keep the plates in a substantially parallel orientation to one another and engage corresponding surfaces.

Applicants refer the Examiner to distractor 238 shown in Fig. 32 of Krueger. Distractor 238 is shown having a body 240 and arms 242. The Examiner asserted that arms 242 read on the claimed tines. As stated in paragraph [0139] of Krueger, "[f]ig. 33 depicts a perspective view of distractor 238 positioned *in* inserter 210. Arms 242 may separate arms 214 of inserter 210. As arms 214 are separated by distractor 238, engaging plates 102, 106 are separated." (emphasis added). As clearly shown and described, arms 214 are what contacts engaging plates 102, 106, not arms 242 of distractor 238. As stated above, "arms 242 may separate arms 214 of inserter 210." Thus, arms 242 are merely a distraction mechanism that are configured to contact and distract arms 214 of inserter 210.

Applicants once again refer the Examiner to paragraph [0146] of the present application which discloses the following:

"[E]ach tong's extent has an upper surface 608a-b and a lower surface 610a-b. The upper surface 608a-b is preferably shaped to conform against the inwardly facing surface of a first (e.g., upper) baseplate of an artificial intervertebral disc, and the lower surface 610a-b is preferably shaped to conform against the inwardly facing surface of a second (e.g., lower) baseplate of the artificial intervertebral disc, so that insertion of the forked distal end of the



leveler 600 between the baseplates, with the central pocket 606 of the distal end avoiding the central portion of the artificial intervertebral disc, and with the upper 608a-b and lower surfaces 610a-b so engaging the inwardly facing surfaces of the baseplates, causes the baseplates to be placed in parallel orientation with respect to one another."

While Applicants reiterate that claims 1 and 17 are not anticipated by Krueger, and are in condition for allowance, Applicants have amended claims 1 and 17 herein to more clearly define the claimed invention. Applicants respectfully assert that amended independent claims 1 and 17 each recite that the tines of the insertion tool engages both inwardly facing surfaces of adjacent baseplates, while in Krueger, only the top surface of extensions 218 of arms 214 engage an inwardly facing surface of one baseplate. The structure of the insertion tool in Krueger (as shown in Fig. 28) thus includes two sets of tines as well as correspondingly shaped inwardly facing contact surfaces of baseplates (namely flat inner surfaces 114 as shown in Fig. 1) in order to effect the orientation of a top baseplate with respect to a bottom baseplate. In contrast, the claimed insertion tool includes only one set or pair of tines in order to bring the baseplates of an artificial intervertebral disc substantially parallel to one another. Thus, the claimed structure of the "one pair of tines" interacting with the structure of the inwardly facing surfaces of the baseplates aids in bringing the baseplates into a parallel orientation, wherein in Krueger, two sets or pairs of tines are utilized to force the baseplates into parallel orientation with one another. In light of the foregoing, Applicants respectfully assert that amended independent claims 1 and 17 are not anticipated by Krueger. Claims 2-5 and 13-16 depending from claim 1 and claims 18, 19, and 21-24 depending from claim 17 are also unanticipated, *inter*

*alia*, by virtue of their dependence from an unanticipated base claim.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: January 25, 2010

Respectfully submitted,  
Electronic signature: /William  
A. Di Bianca/  
William A. Di Bianca  
Registration No.: 58,653  
LERNER, DAVID, LITTENBERG,  
KRUMHOLZ & MENTLIK, LLP  
600 South Avenue West  
Westfield, New Jersey 07090  
(908) 654-5000  
Attorney for Applicants

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